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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,431	01/25/2002	Peter Paasch Mortensen	10127.200-US	9691
25908	7590	10/04/2006	EXAMINER	
NOVOZYMES NORTH AMERICA, INC.			DEJONG, ERIC S	
500 FIFTH AVENUE			ART UNIT	
SUITE 1600			PAPER NUMBER	
NEW YORK, NY 10110			1631	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/057,431		MORTENSEN, PETER PAASCH	
	<b>Examiner</b>		<b>Art Unit</b>	
	Eric S. DeJong		1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20, 28 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED OFFICE ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 and 46 each recite the limitation "the granulation process" in line 2 of claim 45 and in line 2 in claim 46. There is insufficient antecedent basis for this limitation in the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 and 44-46 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Chandler et al. (US Patent No. 6,268,222).

The instant claims are drawn to a method of fluorescence analysis comprising illuminating a granular composition comprising a purified biologically active compound containing a fluorescent marker, detecting light emitted from the fluorescent marker, and predicting the amount of fluorescent marker in the granular composition. The prediction of the amount of fluorescent marker in the granular composition is accomplished by comparing the light emitted therefrom to data on light emitted from a known granular composition.

Chandler et al. sets forth the development of novel fluorescent articles comprising a core particle region having on its surface a plurality of smaller polymeric particles stained with different fluorescent dyes (see Chandler et al., Abstract and throughout). The disclosed fluorescent particles range from 0.1 to 1,000  $\mu\text{M}$  in diameter (see Chandler et al., col. 3, lines 9-20). Chandler et al. further discloses that the composition of the particles may comprise cross-linking agents allowing for the coupling of reactive surfactant agents that allow for interaction with and, subsequently, the detection of antigens, proteins, enzymes, and other biological molecules (see Chandler et al., col. 3, lines 56-62 and col. 4, lines 45-50), which reads on the claimed limitation of the granular composition comprising a biologically active compound. Chandler et al. further set forth that the disclosed particles may be covalently coupled to biological materials including enzymes (see Chandler et al., col. 12, lines 58-64). The fluorescent particles are further disclosed as being capable of emitting a single fluorescence emission or multiple fluorescence emissions with emission spectra ranging from 450 nm to 1000 nm, wherein the different emission maxima of multiple fluorescent dyes are

preferably separated by 20 to 25 nm and are usable with commercially available filters for detecting multiple fluorescence emissions (see Chandler et al., col. 4, lines 15-30). The detection means disclosed for observing and measuring fluorescence emissions includes, digital cameras (CCD) as well as other means for converting observed light into digital signals and two-dimensional images (see Chandler et al., col. 4, line 59 through col. 5, line 4).

Chandler et al. further discloses methods for detecting multiple subpopulations of analytes of interest employing a fluorescent, complementary binding moiety to each of said analytes, wherein each analyte and its complementary binding moiety comprise first and second members of a specific binding pair (see Chandler et al., col. 15, line 38 through col. 16, line 44). The disclosed method includes the steps of forming a mixture of the fluorescently labeled moieties of the binding pair, contacting the mixture and a solid support so that specific binding pairs are formed on solid supports, and relating the presence and concentrations of the analytes of interest in the sample by means of observing and quantifying a resultant fluorescence signal (see Chandler et al., col. 4, line 51 through col. 5, line 42 and Examples 1-11 at col. 16, line 55 through col. 24, line 53). Further, Examples 1 and 3 of Chandler et al. further sets forth an embodiment of the disclosed invention wherein different microparticle samples were stained with a predetermined amount of different fluorescent dyes. The different microparticle samples were further mixed together at different ratios to form a new series of samples. Treating this ratio as an unknown factor, Chandler et al. set forth the empirical determination of the ratio of different microparticles based on the comparison to known data regarding

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the relationship between a particular microparticle concentration and the fluorescence intensity of the specific fluorescent dye used to stain each original collection of microparticles. The fluorescence intensity measured from each of the new series of samples allowed for the determination and back calculation of the particular ratio of different microparticles. Therefore, Chandler et al. sets forth in the above example a demonstration of a calibration model from granular compositions of known quality that, by comparative means, are used to evaluate the quality of samples of unknown quality.

Chandler et al. further sets forth an object of the invention is to provide a novel article, which comprises a microparticle carrying on its surface one or more populations of fluorescently stained nanoparticles (see especially Chandler et al., col. 2, line 63 through col. 3, line 8). All nanospheres in a given population are dyed with the same concentration of a dye, and by coupling a known quantity of these nanospheres to the microparticle (granular composition), along with known quantities of other nanospheres stained with different dyes, a multifluorescent microsphere results. By varying the quantity and ratio of different populations of nanospheres it is possible to establish and distinguish a large number of discreet populations of carrier particles with unique emission spectra. Chandler et al. further sets forth that optimal staining with a particular dye is dependent upon the physical and chemical nature of the individual dye molecules as well as the property being assessed, and sets forth varying both concentration and incubation times in reaction conditions to reach achieve the highest signal (see Chandler et al. col. 10, line 60, though col. 11, line 3. Therefore, Chandler et al. sets forth modeling granular compositions of known quality and changing at least one

process parameter which influences the granulation process used to form the granular composition.

### ***Response to Arguments***

Applicant's arguments filed 07/20/2006 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 U.S.C. § 102(e)(2) as being anticipated by Chandler et al., applicants argue that Chandler does not disclose analyzing the property of granular composition by comparing the amount of emitted light from the granular composition with the same data from a granular composition of known properties.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., comparing the amount of emitted light from the granular composition with the same data from a granular composition of known properties) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is acknowledged that instant claim 1 recites "comparing the amount of emitted light from the granular composition with data on light from a granular composition of known properties" (see claim 1, lines 4-7). It is further reiterated from the above rejection that examples 1 and 3 of Chandler et al. further sets forth an embodiment of the disclosed invention wherein different microparticle samples

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were stained with a predetermined amount of different fluorescent dyes. The different microparticle samples were further mixed together at different ratios to form a new series of samples. Treating this ratio as an unknown factor, Chandler et al. set forth the empirical determination of the ratio of different microparticles based on the comparison to known data regarding the relationship between a particular microparticle concentration and the fluorescence intensity of the specific fluorescent dye used to stain each original collection of microparticles. The fluorescence intensity measured from each of the new series of samples allowed for the determination and back calculation of the particular ratio of different microparticles. Therefore, Chandler et al. sets forth in the above example a demonstration of a calibration model from granular compositions of known quality that, by comparative means, are used to evaluate the quality of samples of unknown quality.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the



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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*John S. Brusca 10 October 2006*  
**JOHN S. BRUSCA, PH.D**  
**PRIMARY EXAMINER**

EDJ

*EDJ*